



UNITED STATES DISTRICT COURT  
FOR THE CENTRAL DISTRICT OF CALIFORNIA  
November 2007 Grand Jury

UNITED STATES OF AMERICA,  
Plaintiff,  
v.  
VINOD CHANDRASHEKM  
PATWARDHAN,  
Defendant.

ED CR 08- 172 VAP  
I N D I C T M E N T  
[21 U.S.C. §§ 331(a), 333(a)(2),  
352(f)(1): Introducing Misbranded  
Drugs into Interstate Commerce;  
18 U.S.C. § 2(b): Causing an Act  
to be Done; 18 U.S.C. § 545:  
Smuggling Goods into the United  
States]

The Grand Jury charges:

INTRODUCTORY ALLEGATIONS

At all times material to this indictment:

1. The United States Food and Drug Administration ("FDA") is the federal agency within the United States Department of Health and Human Services charged with the responsibility for protecting the health and safety of the American public by enforcing the Federal Food, Drug and Cosmetic Act ("FD&C Act"),

1 21 U.S.C. § 301, et seq. One of the purposes of the FD&C Act is  
2 to ensure that all drugs sold for consumption by or  
3 administration to humans and animals are safe and effective for  
4 their intended uses before they may be legally marketed in  
5 interstate commerce and bear labeling containing only true and  
6 accurate information. The FDA's responsibilities under the FD&C  
7 Act include regulating the manufacture, labeling, and  
8 distribution of all drugs and drug components shipped or received  
9 in interstate commerce.

10 2. The FD&C Act defines a "drug" to include, among other  
11 things, any article intended for use in the diagnosis, cure,  
12 mitigation, treatment, or prevention of disease in humans or  
13 other animals; articles (other than food) intended to affect the  
14 structure or any function of the body of humans or other animals;  
15 and articles intended for use as a component of any such  
16 articles. 21 U.S.C. § 321(g).

17 3. The FD&C Act defines "label" as a display of written,  
18 printed, or graphic matter upon the immediate container of any  
19 article. Any requirement under the FD&C Act that a word,  
20 statement, or other information appear on the label shall not be  
21 considered to be complied with unless such word, statement, or  
22 other information also appears on the outside container or  
23 wrapper, if any there be, of the retail package of such article,  
24 or is easily legible through the outside container or wrapper.  
25 21 U.S.C. § 321(k).

26 4. The FD&C Act defines "labeling" as all labels and  
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1 other written, printed, or graphic matters (1) upon any article  
2 or any of its containers or wrappers, or (2) accompanying such  
3 article. 21 U.S.C. § 321(m).

4 5. A drug is misbranded if, among other things, the  
5 labeling on the drug does not bear adequate directions for use.  
6 21 U.S.C. § 352(f)(1).

## COUNTS ONE THROUGH THIRTY-SIX

[21 U.S.C. §§ 331(a), 333(a)(2), 352(f)(1); 18 U.S.C. § 2(b)]

6. The allegations in paragraphs 1-5 of the Indictment are incorporated by reference and realleged as though set forth fully herein.

7. On or about the dates listed below, in San Bernardino County, within the Central District of California, defendant VINOD CHANDRASHEKM PATWARDHAN, with the intent to defraud and mislead, introduced and delivered for introduction into interstate commerce, and caused the introduction and delivery for introduction into interstate commerce of, the items specified below in each Count, each of which were "drugs" within the meaning of the FD&C Act, which were misbranded within the meaning of Title 21, United States Code, Section 352(f)(1), in that they failed to bear adequate directions for use:

COUNT	DATE	ITEM
ONE	12/3/05	20 vials of Celgem 1gm INJ from India to Upland, CA
TWO	1/6/06	10 vials of Zyrop 4000 IU INJ from India to Upland, CA
THREE	1/20/06	20 units of Taxotere 80mg from Honduras to Upland, CA
FOUR	1/20/06	20 units of Avastin 400mg from Honduras to Upland, CA
FIVE	4/6/06	50 vials of Irnocam 100mg from India to Upland, CA

SIX	4/6/06	50 vials of Daxotal 80mg from India to Upland, CA
SEVEN	4/6/06	50 vials of Zolget 4mg from India to Upland, CA
EIGHT	4/6/06	200 vials of Espogen 20,000 from India to Upland, CA
NINE	4/7/06	200 boxes of Emitron 4ml INJ from India to Upland, CA
TEN	4/7/06	50 vials of Oxidach 100mg INJ from India to Upland, CA
ELEVEN	7/29/06	200 boxes of Emitron 4ml INJ from India to Upland, CA
TWELVE	7/29/06	30 vials of Daxotal 80mg from India to Upland, CA
THIRTEEN	7/29/06	100 vials of Espogen 20,000 from India to Upland, CA
FOURTEEN	7/29/06	15 vials of Oxidach 100mg INJ from India to Upland, CA
FIFTEEN	7/29/06	25 vials of Irnozen 100mg from India to Upland, CA
SIXTEEN	8/29/06	15 boxes of Ethyol 500mg from Honduras to Upland, CA
SEVENTEEN	8/29/06	14 vials of Gemzar 1gr from Honduras to Upland, CA
EIGHTEEN	8/29/06	45 vials of Avastin 500mg from Honduras to Upland, CA
NINETEEN	10/2/06	25 vials of Cytogem 1gm INJ from India to Upland, CA

TWENTY	10/2/06	25 vials of Oxidach 100mg INJ from India to Upland, CA
TWENTY-ONE	10/2/06	40 vials of Irnocam 100mg from India to Upland, CA
TWENTY-TWO	10/31/06	30 units of Avastin 400mg from Honduras to Upland, CA
TWENTY-THREE	10/31/06	5 units of Ethyol 500mg from Honduras to Upland, CA
TWENTY-FOUR	10/31/06	10 units of Taxotere 80mg from Honduras to Upland, CA
TWENTY-FIVE	10/31/06	10 units of Rituxan 500mg from Honduras to Upland, CA
TWENTY-SIX	11/19/06	70 vials of Docemil 80mg INJ from India to Upland, CA
TWENTY-SEVEN	11/19/06	200 vials of Espogen 20,000 from India to Upland, CA
TWENTY-EIGHT	11/19/06	40 vials of Oxidach 100mg INJ from India to Upland, CA
TWENTY-NINE	1/2/07	200 vials of Espogen 20,000 from India to Upland, CA
THIRTY	1/2/07	50 vials of Blastozen 4mg INJ from India to Upland, CA
THIRTY-ONE	1/2/07	50 vials of Irnozen 100mg from India to Upland, CA
THIRTY-TWO	1/2/07	10 vials of Oxidach 100mg INJ from India to Upland, CA

THIRTY-THREE	1/2/07	200 boxes Emitron 4ml INJ from India to Upland, CA
THIRTY-FOUR	1/2/07	250 vials of Grafeel 300mcg INJ from India to Upland, CA
THIRTY-FIVE	1/2/07	50 vials of Cytogem 1gm INJ from India to Upland, CA
THIRTY-SIX	1/2/07	20 vials of Docemil 80mg INJ from India to Upland, CA

COUNT THIRTY-SEVEN

[18 U.S.C. § 545]

8. On or about January 3, 2007, in Los Angeles County, within the Central District of California, defendant VINOD CHANDRASHEKM PATWARDHAN fraudulently and knowingly imported and brought into the United States merchandise, namely, 50 vials of Irnozen 100mg, contrary to law.

A TRUE BILL

Foreperson

THOMAS P. O'BRIEN  
United States Attorney

CHRISTINE C. EWELL  
Assistant United States Attorney  
Chief, Criminal Division

SHERI PYM  
Assistant United States Attorney  
Chief, Riverside Office

JOSEPH B. WIDMAN  
Assistant United States Attorney